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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,432	11/23/1998	HOWARD A. FIELDS	03063-0231US	8029

23859 7590 07/30/2002

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EXAMINER
BRUMBACK, BRENDA G

ART UNIT	PAPER NUMBER
1642	31

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/171,432	Applicant(s) FIELDS ET AL.	
	Examiner Brenda G. Brumback	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-82* is/are pending in the application.

4a) Of the above claim(s) *69,73-76 and 79-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-72 and 77-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on 05/21/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/171,432 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed 03/05/2002 has been entered. Claims 70-72 were amended. New claims 77-82 were added.

Please note: Newly submitted claims 79-82 are directed to an invention that is independent or distinct from the invention originally claimed, as they are drawn to species which were nonelected without traverse in Paper #16. Applicant has elected a single species corresponding to the P2A protein for examination on the merits. Claims 79-82 are drawn to peptides comprising at least two HAV proteins which encompass nonelected species. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79-82 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 70-72 and 77-78 are under examination on the merits to the extent that they read on the elected species, the amino acid sequence of a portion of the HAV p2A protein corresponding to SEQ ID NOs:39-46.

Specification

The objection to the specification as not having an abstract submitted on a separate sheet is withdrawn pursuant to applicant's amendment including an abstract.

Claim Objections

Claim 72 and 78 are objected to because of the following informalities:

Claim 72 appears to be missing an article "the" in the second from last line.

Claim 78 appears to be missing either an article or a phrase from line 2 between "of" and "sequence".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 70-72 and 77-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 70-72 for the "substantially similar" language is withdrawn pursuant to applicant's amendment thereof.

The rejection of claims 70 for "a portion" is maintained for the reasons of record. Additionally, newly added claims are rejected under 35 U.S.C. 112, second paragraph, for the reasons of record. Applicant's arguments regarding the "portion" language have been fully considered but they are not persuasive. Applicant's present claims encompass any and all antigenically reactive HAV peptides which comprise any portion of the P2A protein of HAV. A "portion" has been defined as "any fraction up to an including the complete item"; thus, the claimed portion encompasses as little as a single amino acid of the recited sequence. Consequently, applicant's claims encompass virtually all antigenically reactive HAV peptides because all such peptides would be expected to share at least one amino acid in common with the recited P2A protein. For this reason, the metes and bounds of applicant's claimed peptides cannot be determined and the claims are indefinite.

The rejection of claims 70-72 under 35 U.S.C. 112, 2nd paragraph, for "conservative variations" is withdrawn, as applicant's arguments were persuasive.

Regarding the numbering system of the amino acids referenced in the claims, applicant's arguments have been fully considered but they are not persuasive because they do not define a specific reference sequence upon which the claims are based. Absent such definition, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

New Grounds of Rejection:

Claim 71 recites the phrase "can include" in line 2. This phrase renders the claim indefinite, as it is unclear whether the limitations following the phrase are part of the claimed invention (see MPEP § 2173.05(d)).

The term "small" in claim 71 is a relative term, which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 72 is indefinite as the limitation "wherein the amino acid sequence from at least one of SEQ ID NOS:38-43 is excluded" appears to contradict the limitations of claim 70 (from which claim 72 depends), which recites an antigenically reactive HAV peptide comprising a portion of the P2A protein of HAV corresponding to AA 792-980. Applicant has identified AA 792-980 cited in the claims as corresponding to SEQ ID NOS:39-46 in Paper # 20 (filed 03/2//2002). Applicant's proposed claim amendment would thus appear to exclude the same sequences which are specifically recited in the base claim. Clarification and correction are required.

Claim 78 is indefinite because it is unclear if the claim is intended to exclude portions of all of SEQ ID NOS:38-43 or rather, if it is intended to exclude a portion of only a single member that is selected from those of the Markush group.

Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended claim 72 to recite "wherein the amino acid sequence from at least one of SEQ ID NOS:38-43 is excluded" (claim 72). This phrase does not appear to enjoy support in the disclosure as originally filed. This matter might be resolved if applicant were to point out specifically where in the specification support for the newly recited material can be found.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 70-72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chiron Corporation. Newly added claims 77-78 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Chiron Corporation for the reasons of record.

Applicant's arguments have been fully considered but they are not persuasive for the following reasons. Applicant's argument that Chiron neither made nor tested any peptide corresponding to AA 792-848 has been previously addressed. Applicant's proposed claim amendments to eliminate the

"substantially similar" language would not distinguish over Chiron because the proposed claims are drawn to an antigenically reactive HAV peptide comprising an amino acid sequence of a portion of the P2A protein. Therefore, for the reasons set forth *supra*, applicant's claims are not drawn exclusively to a peptide corresponding to AA 792-848, but rather encompass virtually all antigenically reactive HAV peptides.

Applicant further argues that Chiron was wrong in teaching that peptides from the P2A protein would be antigenically reactive and cites Exhibits A-D "as providing evidence of the non-immunogenic nature of the non-structural proteins". This argument, however, is not understood, as each of the articles explicitly teaches that the nonstructural proteins are indeed antigenically reactive in immunoassays and also are immunogenic. Robertson teaches "Serial serum specimens from experimentally infected chimpanzees and humans naturally infected with hepatitis A verified the development of antibodies to P2 protein following infection" (see Exhibit B, the abstract). Robertson also teaches "P2 antibodies in naturally infected humans and experimentally infected chimpanzees appeared to develop during or after liver enzyme elevations" (see Exhibit C, page 78, first sentence of the second column). Jia teaches "All infected individuals tested had antibodies that recognized uncleaved P1 proteins as well as nonstructural proteins" (see Exhibit D, abstract). Thus, each of the referenced exhibits teaches the antigenic reactivity and immunogenicity of the P2 nonstructural protein.

Regarding applicant's argument that Chiron does not suggest any HAV peptide containing less than the complete portion corresponding to amino acids 792-848, applicant is referred to page 18 of the Chiron patent, claim 14, wherein Chiron claims an epitope derived from amino acids 792-848 of the HAV polypeptide sequence. Absent some evidence to the contrary, this would seem to explicitly suggest such a peptide.

Applicant's arguments regarding Chiron and fusion particle-forming proteins associated with HBV surface antigen are noted; however, Chiron specifically teaches individual peptides corresponding

to portions of the P2A protein and specifically teaches making individual " ... polypeptides which may serve either as vaccines themselves, or as intermediates in the production of monoclonal antibody (Mab) preparations useful ... as diagnostic reagents" (see page 3, column 3, lines 2-48).

Applicant's argument that no peptide claimed by any new claim corresponds to the portion of the P2A protein disclosed in Chiron is not understood, as the newly added claims also recite the P2A protein of HAV corresponding to AA 792-980, as is recited in the originally presented claims. Chiron renders such a peptide obvious for the reasons of record.

New Grounds of Rejection:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-72 and 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson et al. (Database PIR_71 on GenCore version 4.5, Accession Nos. PQ0431, PQ0433, PQ0434, PQ0428, PQ0427, PQ0429, PQ0432, and PQ0430, Journal of General Virology, 73:1365-1377, 1992).

The claimed invention is drawn to an isolated antigenically reactive HAV peptide comprising a portion of the amino acid sequence of the P2A protein of HAV corresponding to amino acids (aa) 792-980, which applicant has identified as corresponding to a portion or all of an amino acid sequence selected from SEQ ID NOs:39-46 (see Paper 20).

Robertson et al. teach a fragment of the human HAV (strain No. 4) which comprises SEQ ID NO:39 (see Accession No.PQ0431), a fragment of the human HAV (strain PA21) which comprises SEQ

ID NO:40 and aa 1-10 of SEQ ID NO:41 (see Accession No. PQ0433), and fragments of additional various strains of human HAV, all of which comprise aa 1-10 of SEQ ID NO:41 (see Accession Nos. PQ0434, PQ0428, PQ0427, PQ0429, PQ0432, and PQ0430).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
Primary Examiner